Unacceptable Jessica

Upgrade to paid

The SM-102 cationic lipid (and ALC-0315)

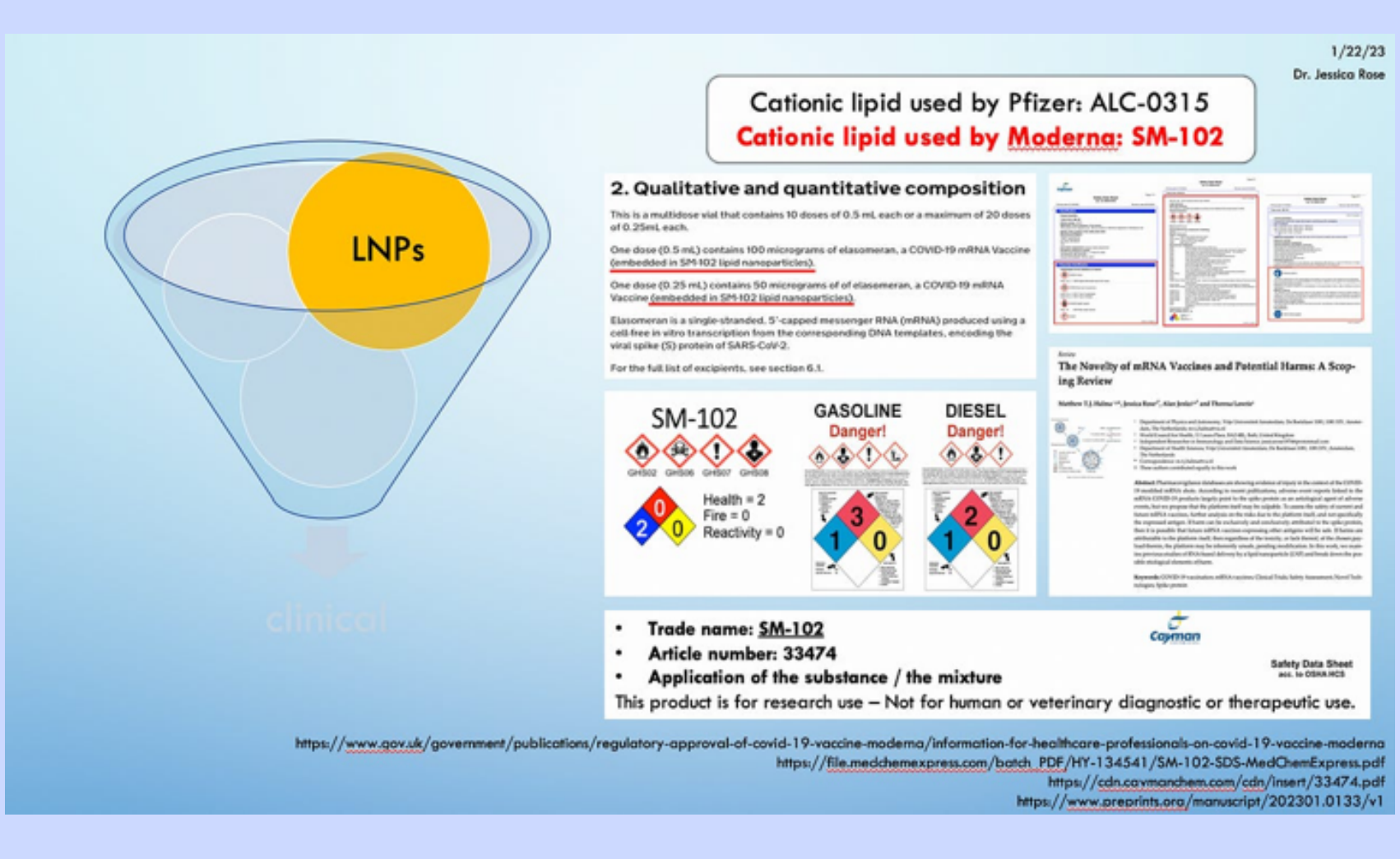
What's the difference between lab and commercial grades?

Jessica Rose
Feb 18

♡321 💬107

This is a very important question to ask for everyone who now knows that Moderna are using the SM-102 cationic lipid as part of their proprietary lipid nanoparticle (LNP) recipe for delivery of their also proprietary modified mRNA.

The reason I say this is a very important question to ask is because I am not sure anybody knows whether or not the cationic lipids used in the LNP formulations by Moderna and Pfizer are lab, or commercial grades. If somebody does know, can you let me know? The [Cayman] Safety Data Sheet (SDS) for the SM-102 cationic lipid refers to a product "not for human or veterinary diagnostic or therapeutic use", so I assume that this particular version of SM-102 is lab grade. But assuming makes an 'ass' out of 'u' and 'me'. We really need to know if the manufacturers have actually adhered to Good Manufacturing Practices (GMPs) and are, in fact, using the United States Pharmacopeia (USP) grade version and not the lab grade version. (I will explain, don't worry.) Because, if they aren't, this would be cataclysmically bad.


1/22/23
Dr. Jessica Rose
Cationic lipid used by Pfizer: ALC-0315
Cationic lipid used by Moderna: SM-102
LNPs
clinical
2. Qualitative and quantitative composition
SM-102
GASOLINE Danger!
DIESEL Danger!
Health = 2
Fire = 0
Reactivity = 0
The Novelty of mRNA Vaccines and Potential Harms: A Scoping Review
Trade name: SM-102
Article number: 33474
Application of the substance / the mixture
This product is for research use – Not for human or veterinary diagnostic or therapeutic use.
Cayman
Safety Data Sheet
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna/information-for-healthcare-professionals-on-covid-19-vaccine-moderna
https://file.medchemexpress.com/batch_PDF/HY-134541/SM-102-SDS-MedChemExpress.pdf
https://cdn.caymanchem.com/cdn/insert/33474.pdf
https://www.preprints.org/manuscript/202301.0133/v1

The slide that seems to be making the rounds from my Sweden talk above refers to the Cayman SDS (for product suspended in ethanol) where it is written that the product is for research use, so this is why I assume that this SM-102 version is lab grade. What is lab grade?

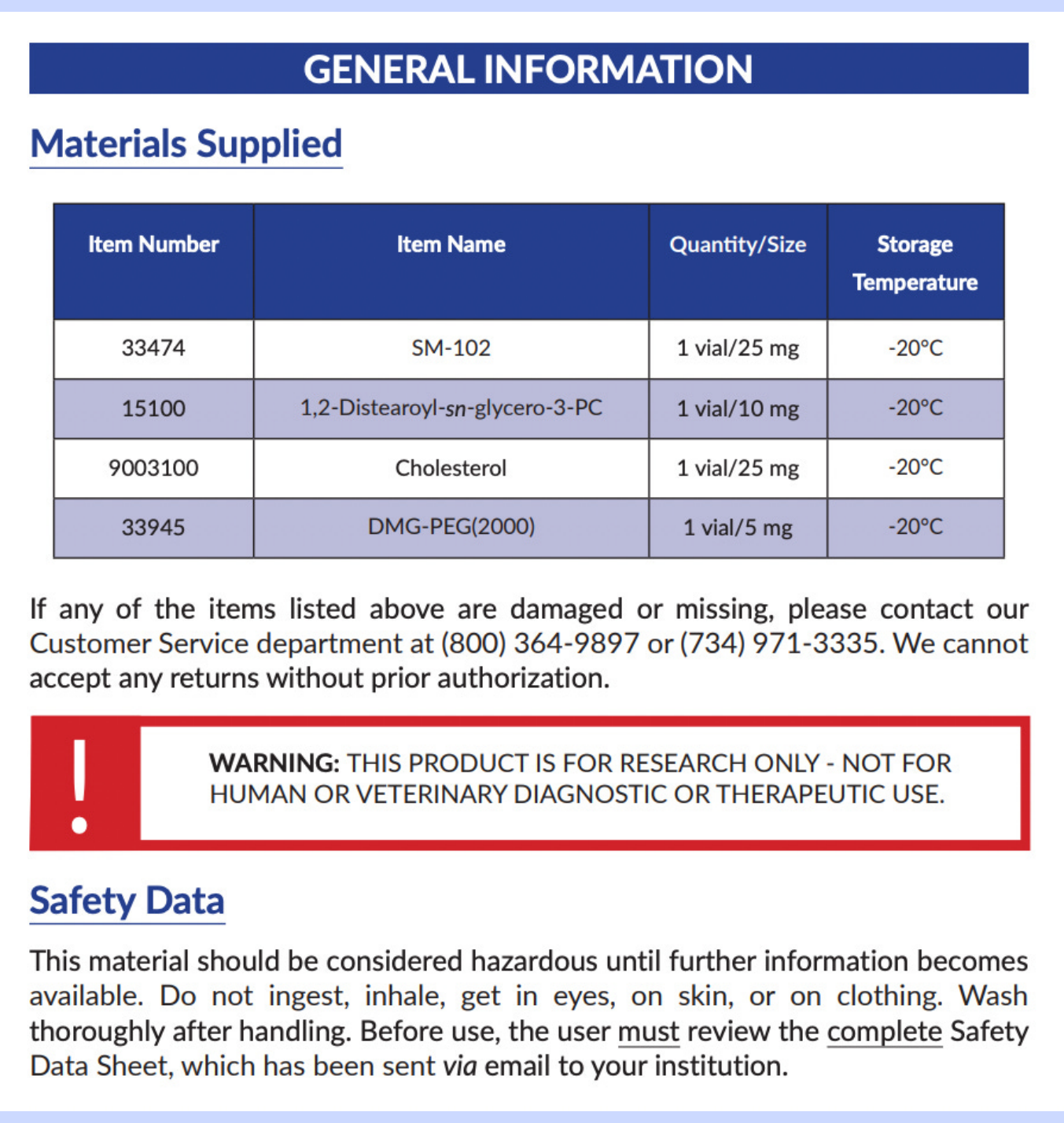
On lab grade

Please refer to Science Company's website for a list of the different quality grades from highest (1) to lowest (7).

> ## 5. Lab
>
> A chemical grade of relatively high quality with exact levels of impurities unknown; usually pure enough for educational applications. Not pure enough to be offered for food, drug, or medicinal use of any kind.

So in other words, not for human use. Agreed? So I think it's safe to say that the SDS refers to a lab grade SM-102 product. It could also be ACS or Reagent grade but both of those wouldn't be for human use either.

Cayman Chemical have their very own LNP kit called Cayman Chemical LIPID NANOPARTICLE (LNP-MC3) KIT. You can buy the kit and make your very own lab grade LNPs. You can perfect the recipe yourself for eventual use in specific contexts - without the need for all that expensive microfluidic mixing equipment! Once you've gotten your mixture and conditions just right, you can move onto commercial grade products for use of your LNP in humans and impress assholes at dinner parties with stories of how you've made billions as a proprietor of some fatty note. Sorry, I can't seem to help myself with these snarky, sarcastic yet clever quips.



GENERAL INFORMATION

Materials Supplied

Item Number	Item Name	Quantity/Size	Storage Temperature
33474	SM-102	1 vial/25 mg	-20°C
15100	1,2-Distearoyl-*sn*-glycero-3-PC	1 vial/10 mg	-20°C
9003100	Cholesterol	1 vial/25 mg	-20°C
33945	DMG-PEG(2000)	1 vial/5 mg	-20°C

If any of the items listed above are damaged or missing, please contact our Customer Service department at (800) 364-9897 or (734) 971-3335. We cannot accept any returns without prior authorization.

! **WARNING:** THIS PRODUCT IS FOR RESEARCH ONLY - NOT FOR HUMAN OR VETERINARY DIAGNOSTIC OR THERAPEUTIC USE.

Safety Data

This material should be considered hazardous until further information becomes available. Do not ingest, inhale, get in eyes, on skin, or on clothing. Wash thoroughly after handling. Before use, the user must review the complete Safety Data Sheet, which has been sent *via* email to your institution.

Cayman Chemical LIPID NANOPARTICLE (LNP-MC3) KIT
https://cdn.caymanchem.com/cdn/insert/35425.pdf

Here's the SDS sheet for the version of SM-102 suspended in ethanol (not chloroform).

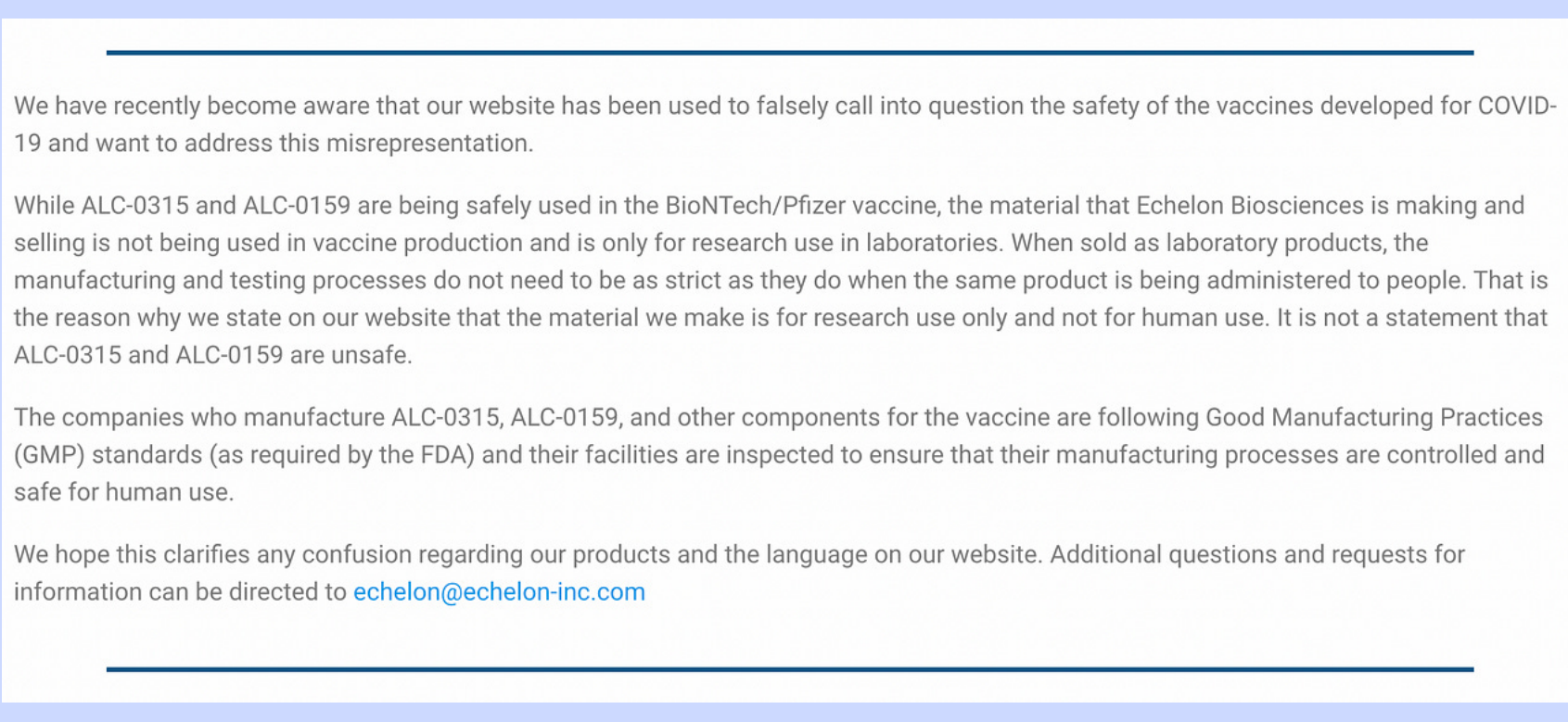
Alrighty then. Everything looks copacetic.

Let's take una pausa. I went on a web search for what people think the difference between a lab and commercial grade product is. I like seeing what real people think. Read the following paragraph that I found in response to a question posted online about lab grade versus commercial grade products.

> Background: I'm a chemist and have worked for companies in Pharma, Research Chemical Supply, and Dietary Supplements.
>
> Lab Grade is different than Food Grade, yes. Normally Food Grade is a **LOWER** quality than Lab Grade.
>
> Lab Grade normally has exhaustive testing on it to determine all impurities. The lab is using this as a reagent and they need to know all that.
>
> Food grade means that it won't cause human disease. So really all they need to know is if there are too many heavy metals or too many bacterial contaminants. The limits are typically higher for food grade.
>
> For instance, when I worked at a Pharmaceutical facility we worked to get a material accepted by FDA as a food grade material and not a Pharma Grade or Reagent Grade. The main reasons were insect and metal parts. The FDA regulations are much more relaxed for food grade and you can have quite a few more of each in the product for food grade than either of the other two.

The FDA regulations are much more relaxed for food grade, eh? Hmm.

Now, read this. This is a disclaimer written by Echelon Biosciences to clear up the unholy mess that me and some other nosy kids have created by learning that certain (lab grade) cationic lipids have a bad score with regard to human health. Worse than gasoline!



We have recently become aware that our website has been used to falsely call into question the safety of the vaccines developed for COVID-19 and want to address this misrepresentation.

While ALC-0315 and ALC-0159 are being safely used in the BioNTech/Pfizer vaccine, the material that Echelon Biosciences is making and selling is not being used in vaccine production and is only for research use in laboratories. When sold as laboratory products, the manufacturing and testing processes do not need to be as strict as they do when the same product is being administered to people. That is the reason why we state on our website that the material we make is for research use only and not for human use. It is not a statement that ALC-0315 and ALC-0159 are unsafe.

The companies who manufacture ALC-0315, ALC-0159, and other components for the vaccine are following Good Manufacturing Practices (GMP) standards (as required by the FDA) and their facilities are inspected to ensure that their manufacturing processes are controlled and safe for human use.

We hope this clarifies any confusion regarding our products and the language on our website. Additional questions and requests for information can be directed to echelon@echelon-inc.com

https://www.echelon-inc.com/statement-on-alc-lipids/

So these biotech guys are claiming the opposite of the chemistry guy. They claim that the lab grade stuff undergoes less strict manufacturing and testing processes than the stuff being administered to people. So which is it? Who's right? Generally, one would seek out ACS[1] or Reagent grade[2] for lab work since when you're mixing chemicals, you kind of want to mix the things that you want to mix, and not other stuff.

> The companies who manufacture [the cationic lipids] and other components for the vaccine are following Good Manufacturing Practices (GMP) standards (as required by the FDA) and their facilities are inspected to ensure that their manufacturing processes are controlled and safe for human use.

Ok. Why don't I feel re-assured here? Are the FDA doing their job and checking in on our little LNP production fairies to make sure that they are using commercial-grade products? The trusty pharmaceutical companies would NEVER rush safety trials or use lab grade products, would they? They would always use USP or National Formulary (NF) grade products. Right?

Well let me ask you something. Do you trust the FDA after what they've done over the past 3 years? I don't.

On commercial grade

Again, please refer to Science Company's website for a list of the different quality grades from highest (1) to lowest (7).

3. U.S.P.

> A chemical grade of sufficient purity to meet or exceed requirements of the United States Pharmacopeia (USP); acceptable for food, drug, or **medicinal use**; may be used for most laboratory purposes.

4. N.F.

> A grade of sufficient purity to meet or exceed requirements of the United States National Formulary. (Since bought out and merged with the United States Pharmacopeia, USP-NF.) THM: it's the same as USP.

Ok, so like we talked about, the SM-102 and the ALC-0315 cationic lipids used to make the LNPs by Moderna and Pfizer, respectively, must meet either one of these standards in order for them to be appropriate for use in humans, right? Let's visit the USP website. You can sign in and download their Analytical Procedures for mRNA Vaccine Quality Draft Guidelines. I did. You can find that here. Teehee, I just learned that I can drag and drop pfds! Thanks Jikky.

Ea966w Mrna Vaccine Chapter 2022 02 1
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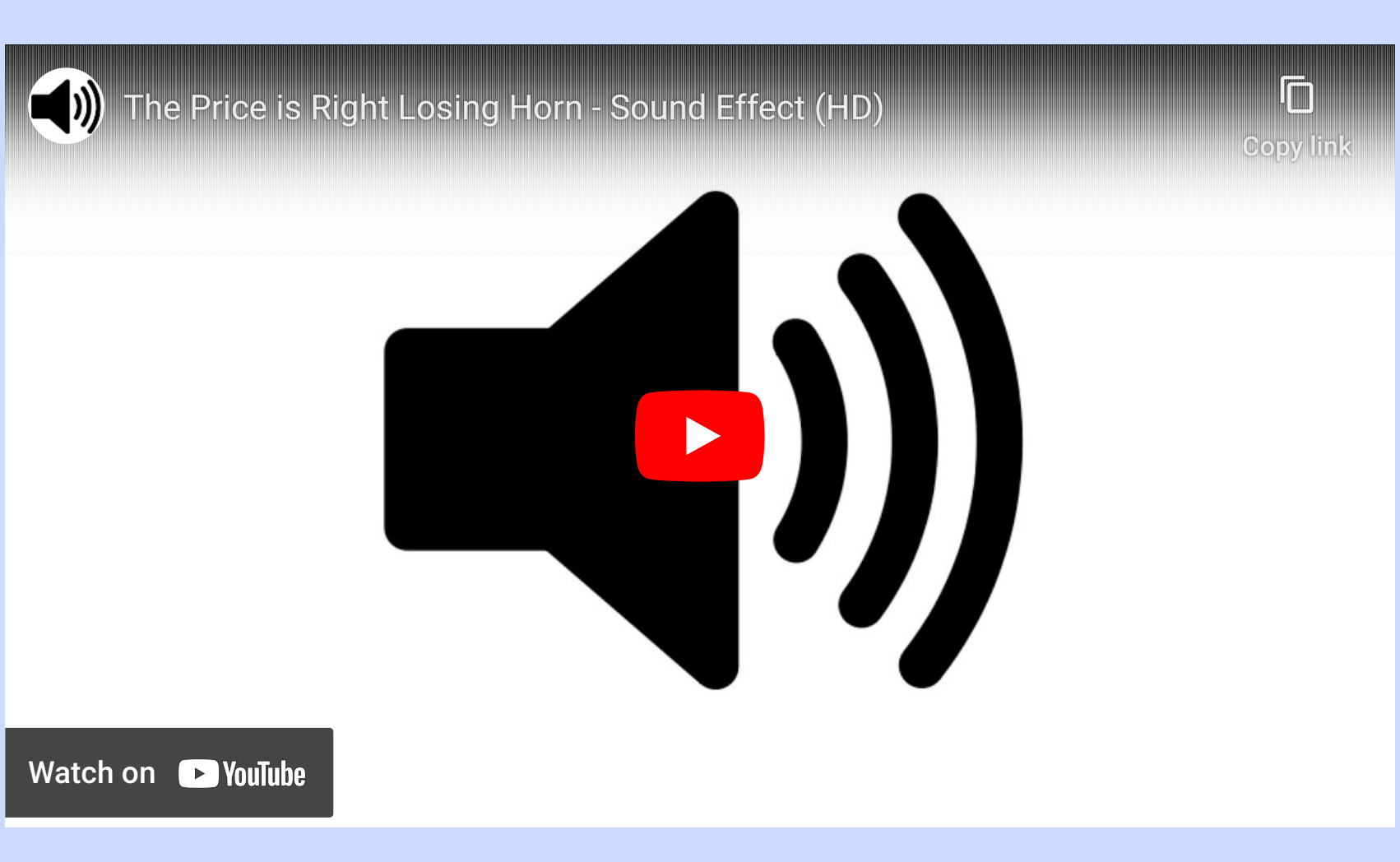
I was so excited to finally learn where the 'safe and effective' mantra came from and to finally be proven wrong about my worries concerning lacking GMPs and upscaling abilities!



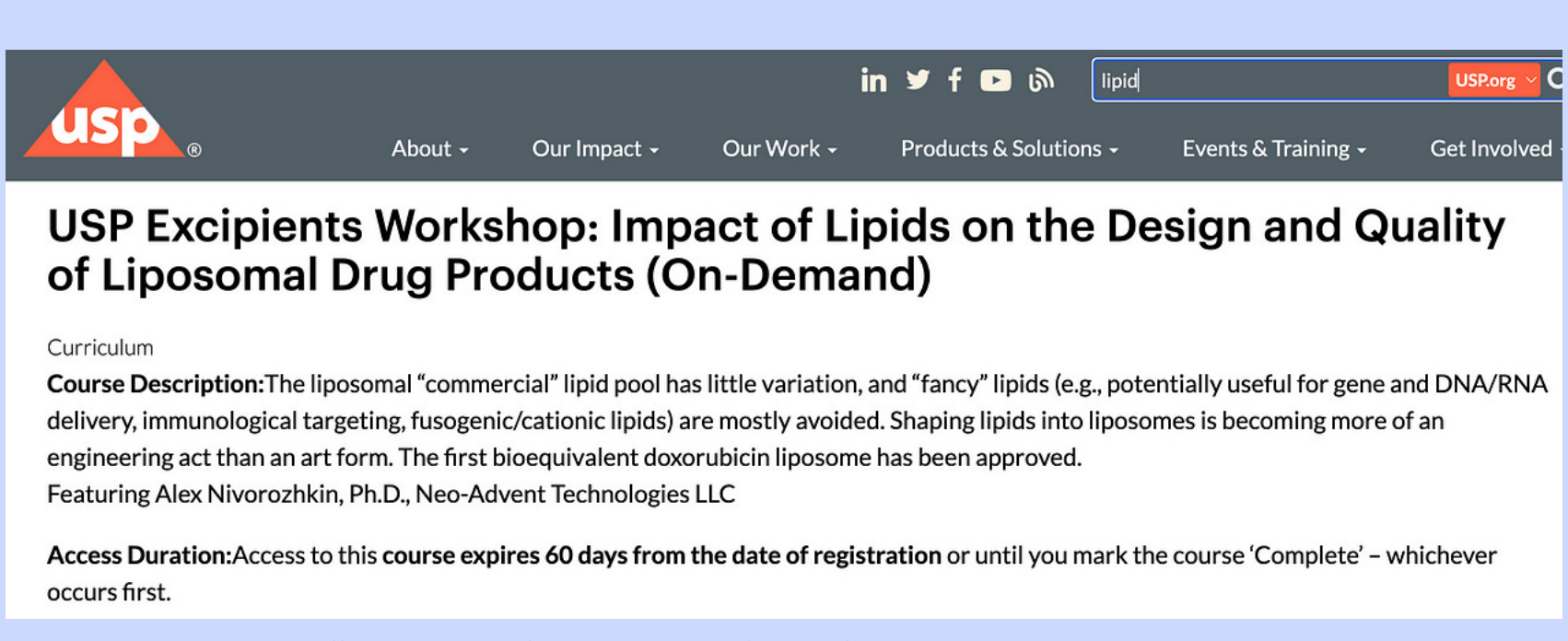
Quote from Analytical Procedures for mRNA Vaccine Quality Draft Guidelines:

> Since the successful application of mRNA technology is relatively new, regulatory guidelines and industry standards to guide non-proprietary aspects of mRNA quality during development and manufacturing **are still evolving**. These include areas such as verifying the identity of the drug substance, **controlling impurities** and measuring content for dosing. Without a common set of methods for determining quality, developers and manufacturers of mRNA products must develop their own in-house methods and protocols, taking attention and resources away from a company's successful application of mRNA technology unique to the medical product.

What was that someone said once? Something about learning to build the plane mid-flight or something?

I read the whole thing and there's a lot of stuff about how to make and quality control the mRNA. But the fact that they admit that 'non-proprietary aspects of mRNA quality during development and manufacturing **are still evolving**' disturbs me and I also have to wonder about the propriety aspects since, well, they're private. The public should be able to have access to details on what they're being injected with, shouldn't they? From both 'companies', right? They're also looking for helpful input, by the way. If you happen to have any. Upscaling issues are not sufficiently addressed either.

But we want to know about the LNPs and cationic lipids. Wait now, there's no section on LNPs. How can that be? I want to see the same rigorous pdf write-up for LNPs. I tried the keywords 'cationic', 'lipid nanoparticle', 'SM-102' and 'ALC-0315' in the search bar, and the USP website turned up nothing. The only return I got was for the keyword 'lipid' and it's bizarre. Why do they describe the lipids potentially used for RNA delivery as "fancy" and what does 'mostly avoided' mean?



USP Excipients Workshop: Impact of Lipids on the Design and Quality of Liposomal Drug Products (On-Demand)

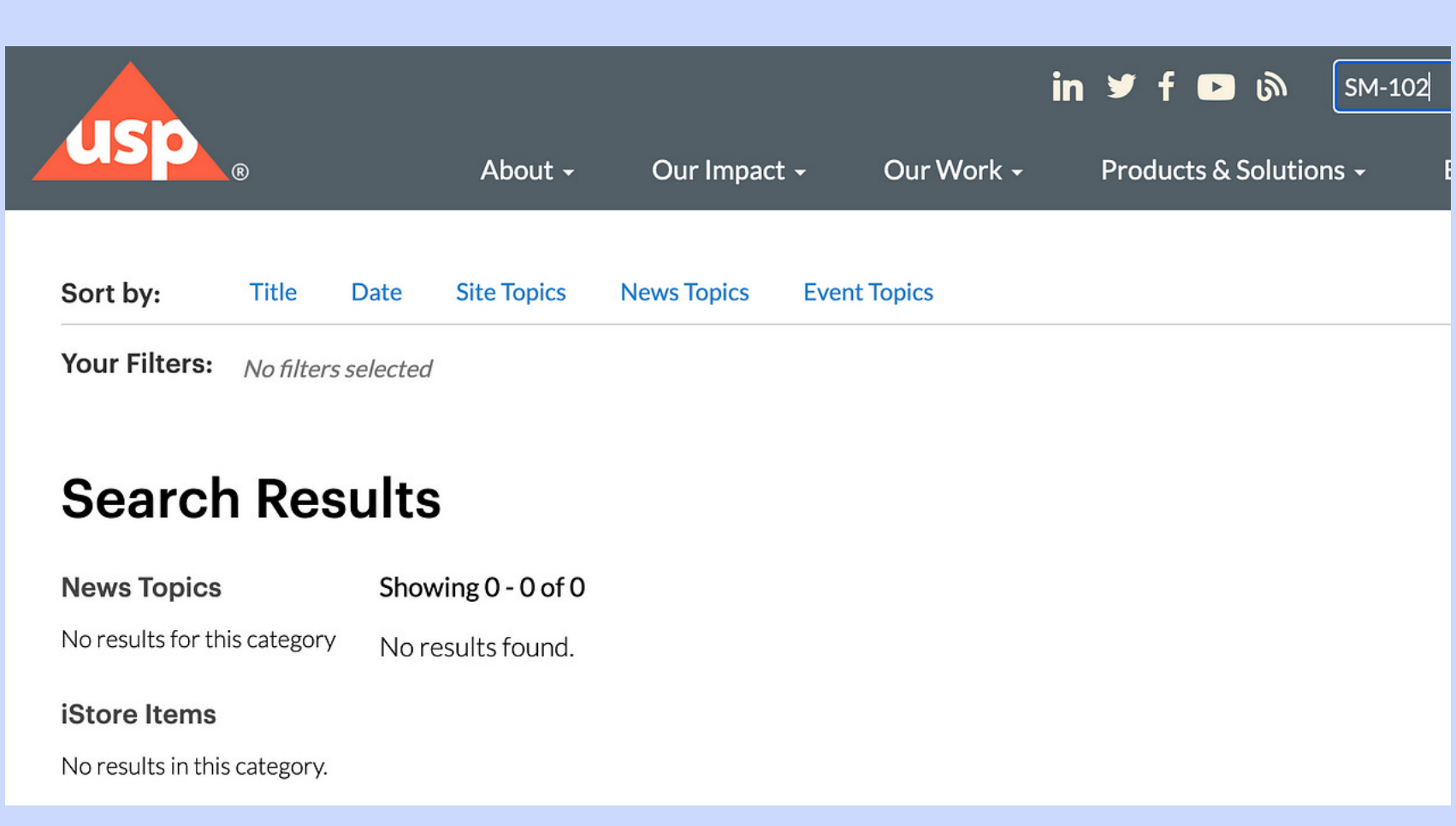
Curriculum

Course Description: The liposomal "commercial" lipid pool has little variation, and "fancy" lipids (e.g., potentially useful for gene and DNA/RNA delivery, immunological targeting, fusogenic/cationic lipids) are mostly avoided. Shaping lipids into liposomes is becoming more of an engineering act than an art form. The first bioequivalent doxorubicin liposome has been approved.
Featuring Alex Nivorozhkin, Ph.D., Neo-Advent Technologies LLC

Access Duration: Access to this **course expires 60 days from the date of registration** or until you mark the course 'Complete' – whichever occurs first.

https://www.usp.org/events-training/course/usp-excipients-workshop-impact-lipids-design-and-quality-liposomal-drug

Is this not how one seeks information of USP standards associated with a product? It worked for Vitamin C and Ivermectin (that they refer to in BLOCK LETTERS as a dangerous good) and Remdesivir and cholesterol. Maybe it's because the LNPs don't comprise the 'product' because they are part of 'packaging'? But then how does one quality-control-check the packaging? All chemicals can and should be graded so like I said, the cationic lipids used in the COVID shots *MUST* have a USP grade, right? Or some grade, other than a lab grade, right?



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https://www.usp.org/search?search_api_fulltext=ALC-0315

Where are the commercial grades for the cationic lipids documented? This is one of those times when it's getting late and I feel like my own sleuthing skills have been maxed out. Maybe one of my crafty readers can find it.

I actually really, really want to find this.

I going to leave this hanging for now. I have no answer to my original question as to whether or not Moderna and Pfizer are using USP grade cationic lipids, etc, in their LNP formulations. So beyond assuming that they are making these cationic lipids themselves using the most astonishingly pristine GMPs to product grade-USP products, I have to assume that they might not be. I might even assume that they are using lab grade products.

Someone please prove me wrong.

Oh, by the way, the only one of the 7 grades listed with the actual word 'commercial' in it the description is the last one called Technical grade.

7. Technical

> Good quality chemical grade used for commercial and industrial purposes. Not pure enough to be offered for food, drug, or medicinal use of any kind.

I wonder if they might be using this grade. It's both a commercial and an industrial operation to produce billions of doses of products after all, isn't it? The only thing is, it's not for use in humans.

Maybe go back to The Price is Right horn to end this Substack with an uncomfortable laugh.

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[1] A chemical grade of highest purity and meets or exceeds purity standards set by American Chemical Society (ACS). https://www.sciencecompany.com/Learn-Chemical-Grade-Definitions-from-Highest-to-Lowest-Purity..aspx

[2] High purity generally equal to A.C.S. grade and suitable for use in many laboratory and analytical applications. https://www.sciencecompany.com/Learn-Chemical-Grade-Definitions-from-Highest-to-Lowest-Purity..aspx

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107 Comments

Write a comment...

Warrior Writes Beyond Treason Feb 18

So this is just one of hundreds of VALID red flag warnings.

Just imagine the arrogance of a government or health authority or worse a corporation that sells a product as good for you, safe for you, and it will be forcefully injected into billions YET THEY REFUSE TO TELL YOU WHAT ALL OF THE INGREDIENTS ARE.

THIS was a major warning from day one . Yes , even the most famous accomplished doctors globally including as example Dr. Paul Marik (FLCCC) tried to ask and demand a list , and was shot down.

So now let's also point out that both SM- 102 and PEG (poly ethylene glycol) are extremely DANGEROUS to human health .

These are NOT NATIVE molecules to the human body . In themselves they can cause INJURY and death .

Worse nano particles are NOT NEW and how they are encapsulated to deliver their payload matters.

For example Lipisomal Vitamin C and a plethora of other lipid nano particles have been used for DECADES.

Historically to ensure safety these healthy supplents ALWAYS use phosphoidylcholine, a well known phospholipid that is found in the human body that surrounds and creates the complex cellular membrane . This is cellular biology 101 and not rocket science .

But let's dig deeper . What 99 percent of humans FAILED to realize is the word NANOMETER.

A nanometer is one BILLIONTH of a meter. Often in science we use MICRONS which are a millionth

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10 replies

Linda Reed Feb 18 ♥ Liked by Jessica Rose

Thanks once again, Jessica, for letting the Pharma creeps know that someone is watching. I'm appalled at the level of greed and pure evil that has allowed this medical catastrophe to develop.

And I, too, like your snarky comments.

♡ 46 Reply Gift a subscription Collapse •••

105 more comments...

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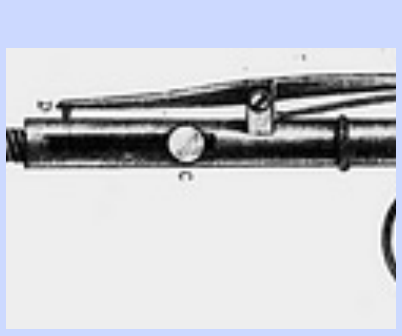
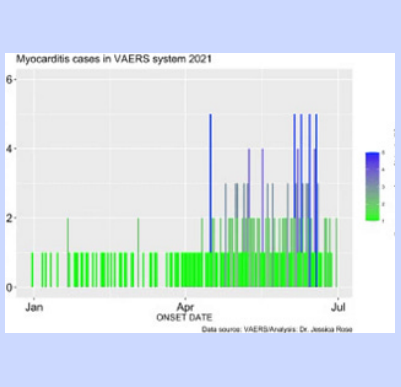
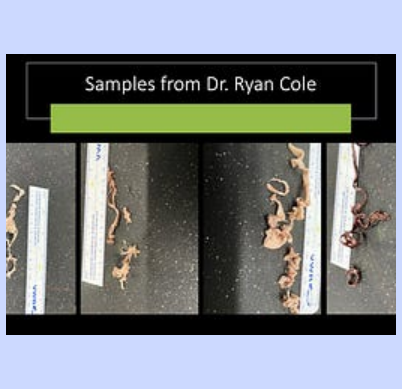


This is one of the emails I received the other day. I get hundreds daily, and I am hearing you all.
This particular note spoke loudly to me and this lovely person gave me permission to share her words.
JESSICA ROSE JUL 17, 2022 ♡1,699 💬246



A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable…
Jessica Rose PhD, MSc, BSc and Peter A. McCullough MD, MPH
JESSICA ROSE NOV 2, 2021 ♡1,258 💬146



Rewrite: Let's tag team this until everybody understands
The modified spike protein is dangerous and for very specific reasons.
JESSICA ROSE JUN 13, 2022 ♡698 💬140

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